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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/728,577

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

NOTIFICATION DATE

DELIVERY MODE

12/01/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/728,577	Applicant(s) BURTON ET AL.	
	Examiner BLESSING M. FUBARA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-26, 60 and 75-121 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 2-26, 60 and 75-121 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1618

DETAILED ACTION

The examiner acknowledges receipt of IDS amendment and remarks filed 8/21/2008.

Claims 71 and 74 are cancelled. Claims 2-7, 9, 11, 13, 15, 17-22, 60, 75 and 76 are amended.

New claims 77-121 are added. Claims 2-26, 60 and 75-121 are pending.

Upon further consideration and review, previous rejections have been withdrawn. A restriction requirement is being made due to the complexity of the invention, which will be explained in the following restriction. No call was made due to the complexity of the claimed subject matter. The inventions are so different that they cannot be searched together; it will be a burden on the examiner to search all the inventions as has been claimed.

For example, A) it will be a burden on the examiner to search all the inventions as has been claimed because, polylactam containing organic polymer is a different class of polymer, which is structurally different from poly(quaternary amine) containing organic polymer.

B) There is no correlation between these two different classes of compounds. And therefore, the search for polylactam containing organic polymer will not be the same as the search for poly(quaternary amine) containing organic polymer.

Please note new claims 77, 79, 82 and 85 read:

77. (New) A wound dressing comprising an apertured, liquid permeable substrate and a polymer composition preparable by a method comprising combining components comprising:

an organic polymer matrix;

a continuous hydrophobic liquid phase and absorbent hydrophilic polymer microparticles dispersed within the hydrophobic liquid phase, wherein the microparticles when in a

Art Unit: 1618

substantially nonhydrated form have an average particle size of 10 microns or less, and wherein the microparticles comprise a poly(quaternary amine)-containing organic polymer;

a bioactive agent selected from the group consisting of a silver compound, a copper compound, a zinc compound, and combinations thereof, wherein the silver compound has a solubility in water of at least 0.1 gram per liter; and

an optional foaming agent;

wherein the components are combined in a manner to produce a polymer mixture comprising the organic polymer matrix and the microparticles, wherein at least a portion of the bioactive agent is incorporated within the microparticles; and

wherein the microparticles are present in an amount of 1 wt-% to 60 wt-%, based on the total weight of the polymer composition.

79. (New) A wound dressing comprising an apertured, liquid permeable substrate and a polymer composition preparable by a method comprising combining components comprising:

an organic polymer matrix;

a continuous hydrophobic liquid phase and absorbent hydrophilic polymer microparticles dispersed within the hydrophobic liquid phase, wherein the microparticles when in a substantially nonhydrated form have an average particle size of 10 microns or less, and wherein the microparticles comprise a polylactam-containing organic polymer,

Art Unit: 1618

a bioactive agent selected from the group consisting of a silver compound, a copper compound, a zinc compound, and combinations thereof, wherein the silver compound has a solubility in water of at least 0.1 gram per liter; and

an optional foaming agent;

wherein the components are combined in a manner to produce a polymer mixture comprising the organic polymer matrix and the microparticles, wherein at least a portion of the bioactive agent is incorporated within the microparticles;

wherein the microparticles are present in an amount of 1 wt-% to 60 wt-%, based on the total weight of the polymer composition; and

wherein the polymer composition when coated on a substrate displays a 180" peel strength from stainless steel of less than 1 N/cm.

82. (New) A wound dressing comprising an apertured, liquid permeable substrate and a polymer composition preparable by a method comprising: combining components comprising:

an organic polymer matrix;

a continuous hydrophobic liquid phase and absorbent hydrophilic polymer microparticles dispersed within the hydrophobic liquid phase, wherein the microparticles when in a substantially nonhydrated form have an average particle size of 10 microns or less, and wherein the microparticles comprise a poly(quaternary amine)-containing organic polymer;

Art Unit: 1618

a bioactive agent selected from the group consisting of a silver compound, a copper compound, a zinc compound, and combinations thereof, wherein the silver compound has a solubility in water of at least 0.1 gram per liter;

and an optional foaming agent;

wherein the components are combined in water in a manner to produce a polymer mixture comprising the organic polymer matrix and the microparticles, wherein at least a portion of the bioactive agent is incorporated within the microparticles; and

removing a substantial portion of the water to form the polymer composition.

85. (New) A wound dressing comprising an apertured, liquid permeable substrate and a polymer composition preparable by a method comprising:

combining components comprising:

an organic polymer matrix;

a continuous hydrophobic liquid phase and absorbent hydrophilic polymer microparticles dispersed within the hydrophobic liquid phase, wherein the microparticles when in a substantially nonhydrated form have an average particle size of 10 microns or less, and wherein the microparticles comprise a polylactam-containing organic polymer;

a bioactive agent selected from the group consisting of a silver compound, a copper compound, a zinc compound, and combinations thereof, wherein the silver compound has a solubility in water of at least 0.1 gram per liter; and

Art Unit: 1618

an optional foaming agent;

wherein the components are combined in water in a manner to produce a polymer mixture comprising the organic polymer matrix and the microparticles, wherein at least a portion of the bioactive agent is incorporated within the microparticles; and

removing a substantial portion of the water to form a polymer composition, wherein the polymer composition when coated on a substrate displays a 180" peel strength from stainless steel of less than 1 N/cm.

As identified by applicant on 14 of 19 of the response filed 8/21/08, claims 79 and 85 having the microparticles to contain the polylactam-containing organic polymer are restricted from claims 77 and 82 having the microparticles contain the poly(quaternary amine) containing organic polymer as described below.

Restriction Requirements

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 77, 78, 2-17, 19-26, 60 and 75 (claim 77 and dependent claims), 82, 18, 76, 83, 84 and 88-107 (claim 82 and dependent claims), drawn to wound dressing composition in which the microparticles dispersed in the hydrophobic liquid phase comprise poly(quaternary amine) containing organic polymer, classified in class 424, subclass 489.
 - II. Claims 79-81, 108-115 (claim 79 and dependent claims), 85-87, 116-121 (claims 85 and dependent claims) drawn to wound dressing composition in which the

Art Unit: 1618

microparticles dispersed in the hydrophobic liquid phase comprise polylactam-containing organic polymer, classified in class 424, subclass 486.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs.

3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Art Unit: 1618

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Election of Species Requirement

4. Claims 77, 79, 82 and 85 are generic to the following disclosed patentably distinct species: a) elastomeric, thermoplastic and hydrophilic; b) form of the composition is extrudate or foam. The species are independent or distinct because as disclosed the different species have

Art Unit: 1618

mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

5. In either case, if applicant elects Group I or Group II, applicant is further requested to elect i) elastomeric or thermoplastic or hydrophilic; ii) extrudate or foam;
6. If applicant elects hydrophilic, applicant is also requested to elect a single hydrophilic polymer for prosecution;
7. If applicant elects elastomeric polymer, applicant is also requested to elect a single elastomeric polymer;
8. If applicant elects a thermoplastic polymer, applicant is also requested to elect a specific thermoplastic polymer

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including

Art Unit: 1618

any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1618

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Examiner, Art Unit 1618